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May 21, 2024

VIA ECF

Honorable Sharon A. King, U.S.M.J.
United States District Court
Mitchell H. Cohen U.S. Courthouse
4th and Cooper Streets
Camden, New Jersey 08101

Re: *Novo Nordisk Inc., et al. v. Rio Biopharmaceuticals, Inc.*
Civil Action Nos. 24-330 & 24-688 (RMB)(SAK)

Dear Judge King:

This firm, together with Fenwick & West LLP, represents Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S in the above-captioned matters.

Enclosed is the parties' Joint Proposed Discovery Plan. We look forward to discussing this and any other issue Your Honor wishes to address during the Initial Scheduling Conference on May 28, 2024 at 2:00 p.m.

Thank you for Your Honor's kind attention to these matters.

Respectfully yours,

A handwritten signature in blue ink, reading "Charles M. Lizza".

Charles M. Lizza

Enclosure

cc: All counsel (via email)

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**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

NOVO NORDISK INC. and
NOVO NORDISK A/S,

Plaintiffs,

v.

RIO BIOPHARMACEUTICALS, INC.,

Defendant.

C.A. No. 24-cv-330 (RMB)(SAK)
C.A. No. 24-cv-688 (RMB)(SAK)

**Initial Scheduling Conference:
May 28, 2024 at 2:00 p.m.**

(Filed Electronically)

JOINT PROPOSED DISCOVERY PLAN

Pursuant to Federal Rules of Civil Procedure 16 and 26(f) and Local Civil Rule 26.1(b), Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, “Novo Nordisk” or “Plaintiffs”) and Defendant Rio Biopharmaceuticals, Inc. (“Rio” or “Defendant”) have conferred and submit the following Joint Discovery Plan.

1. Set forth a factual description of the case. Include the causes of action and affirmative defenses asserted.

Joint Response (C.A. No. 24-330): This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, filed by Novo Nordisk in response to Rio's submission of Abbreviated New Drug Application ("ANDA") No. 218241 ("Rio's Victoza[®] ANDA") with the United States Food and Drug Administration ("FDA").

Rio is seeking approval from the FDA to commercially market a generic version of Novo Nordisk's Victoza[®] (liraglutide injection solution, 18 mg/ 3 ml (6 mg/ml)) before the expiration of U.S. Patent Nos. 8,114,833 (the "'833 patent") and 9,265,893 (the "'893 patent") (collectively, the "Victoza[®] patents-in-suit"), both of which are owned by Novo Nordisk A/S.

This litigation was commenced following Novo Nordisk's receipt of a notice letter from Rio in which Rio stated that it seeks to commercially market a generic version of Novo Nordisk's Victoza[®] (liraglutide injection solution, 18 mg/ 3 ml (6 mg/ml)) before the expiration of the Victoza[®] patents-in-suit. The Victoza[®] patents-in-suit cover, among other things, pharmaceutical formulations and aspects of injection pen devices.

Novo Nordisk asserts that Rio's ANDA submission constitutes infringement of one or more claims of each of the Victoza[®] patents-in-suit. Rio denies infringement of the Victoza[®] patents-in-suit and alleges that the Victoza[®] patents-in-suit are invalid and/or unenforceable.

Joint Response (C.A. No. 24-688): This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, filed by Novo Nordisk in response to Rio's submission of ANDA No. 218240 ("Rio's Saxenda[®] ANDA") with the FDA.

Rio is seeking approval from the FDA to commercially market a generic version of Novo Nordisk's Saxenda[®] (liraglutide injection solution, 18 mg/ 3 ml (6 mg/ml)) before the expiration of the '833 patent, 8,684,969 (the "'969 patent"), 8,920,383 (the "'383 patent"), 9,108,002 (the "'002 patent"), 9,132,239 (the "'239 patent"), 9,457,154 (the "'154 patent"), 9,616,180 (the "'180 patent"), 9,687,611 (the "'611 patent"), 9,775,953 (the "'953 patent"), 9,861,757 (the "'757 patent"), 10,220,155 (the "'155 patent"), 10,357,616 (the "'616 patent"), 10,376,652 (the "'652 patent"), 11,097,063 (the "'063 patent"), 11,311,679 (the "'679 patent"), 11,446,442 (the "'443 patent"), and RE46,363 (the "'363 patent") (collectively, the "Saxenda[®] patents-in-suit"), all of which are owned by Novo Nordisk A/S.

This litigation was commenced following Novo Nordisk's receipt of a notice letter from Rio in which Rio stated that it seeks to commercially market a generic version of Novo Nordisk's Saxenda[®] (liraglutide injection solution, 18 mg/ 3 ml (6 mg/ml)) before the expiration of the Saxenda[®] patents-in-suit. The Saxenda[®] patents-in-suit cover, among other things, pharmaceutical formulations and aspects of injection pen devices.

Novo Nordisk asserts that Rio's ANDA submission constitutes infringement of one or more claims of each of the Saxenda[®] patents-in-suit. Rio denies infringement of the Saxenda[®] patents-in-suit and alleges that the Saxenda[®] patents-in-suit are invalid and/or unenforceable.

2. **C.A. Nos. 24-330 and 24-688**

Have settlement discussions taken place? Yes X No .

(a) **What was Plaintiffs' last demand?**

(1) Monetary demand: \$ N/A

(2) Non-monetary demand:

(b) **What was Defendant's last offer?**

(1) Monetary demand: \$ N/A

(2) Non-monetary demand:

3. **The parties have have not X exchanged the information required by Fed. R. Civ. P. 26(a)(1). If not, state the reason therefor.**

Joint Response (C.A. Nos. 24-330 & 24-688): The parties' proposed date for exchange of Rule 26(a)(1) disclosures is in the proposed schedule attached hereto as Exhibit 1.

4. **Describe any discovery conducted other than the above disclosures.**

Joint Response (C.A. Nos. 24-330 & 24-688): Rio has produced ANDA Nos. 218240 and 218241. Otherwise, no discovery has occurred in this litigation.

5. **Generally, dispositive Motions cannot be filed until the completion of discovery. Describe any Motions any party may seek prior to the completion of discovery. Include any jurisdictional Motions and Motions to Amend.**

Joint Response (C.A. Nos. 24-330 & 24-688): At present, the parties do not plan to seek to file dispositive motions before the completion of discovery. The parties are not aware of any non-dispositive motions at this time, but they may seek to file such motions before the completion of expert discovery, including, for example, discovery motions or motions to amend in accordance with the proposed case schedule in Exhibit 1. Of course, the parties will meet and confer before filing any discovery motions.

6. **The parties proposed the following:**

(a) **Discovery is needed on the following subjects:**

Joint Response (C.A. Nos. 24-330 & 24-688): Discovery relating to the claims and defenses in the parties' pleadings, including infringement and validity of the Victoza[®] patents-in-suit and the Saxenda[®] patents-in-suit, as well as various related issues, claims, and affirmative defenses.

(b) **Should discovery be conducted in phases? If so, explain.**

Joint Response (C.A. Nos. 24-330 & 24-688): Discovery should not be conducted in phases.

(c) Number of Interrogatories by each party to each other party:

Joint Response (C.A. Nos. 24-330 & 24-688): The Federal Rules of Civil Procedure provide a sufficient starting point for the number of Interrogatories served by each side. Accordingly, the parties provisionally agree that each side be allowed to serve up to 25 Interrogatories in each case. Discrete subparts of an Interrogatory will be counted individually against the total permitted. Should the need arise, the parties can discuss the possibility of additional Interrogatories in the future.

(d) Number of Depositions by each party to each other party:

Joint Response (C.A. Nos. 24-330 & 24-688): The Federal Rules of Civil Procedure provide a sufficient starting point for the number of Depositions served by each side. Accordingly, no change to Fed. R. Civ. P. 30(a)(2)(A)(i) regarding depositions is requested. To the extent a witness is relevant to both C.A. Nos. 24-330 and 24-688, the parties agree that the witness will only be deposed once, that the deposition will be admissible in both C.A. Nos. 24-330 and 24-688, and that the deposition will count towards each case's limit under the Federal Rules of Civil Procedure. Should the need arise, the parties can discuss the possibility of additional Depositions in the future. No single deposition shall last more than 7 hours on the record, except that any deposition of a witness testifying in a foreign language may last no more than 10.5 hours on the record. These time limits shall apply regardless of whether the witness is being deposed in a personal capacity, as a 30(b)(6) designee, or both.

(e) Plaintiffs' expert report due on _____:

Joint Response (C.A. Nos. 24-330 & 24-688): The parties' proposed schedule is attached hereto as Exhibit 1.

(f) Defendants' expert report due on _____:

Joint Response (C.A. Nos. 24-330 & 24-688): The parties' proposed schedule is attached hereto as Exhibit 1.

(g) Motion to Amend or to Add Parties to be filed by _____:

Joint Response (C.A. No. 24-330 & 24-688): The parties' proposed schedule is attached hereto as Exhibit 1.

(h) Dispositive motions to be served within _____ days of completion of discovery:

Joint Response (C.A. Nos. 24-330 & 24-688): The parties agree that dispositive motions would be inappropriate in these cases.

(i) Factual discovery to be completed by _____:

Joint Response (C.A. Nos. 24-330 & 24-688): The parties' proposed schedule is attached hereto as Exhibit 1.

(j) Expert discovery to be completed by _____:

Joint Response (C.A. Nos. 24-330 & 24-688): The parties' proposed schedule is attached hereto as Exhibit 1.

(k) Set forth any special discovery mechanism or procedure requested, including data preservation orders or protective orders:

Joint Response (C.A. Nos. 24-330 & 24-688): A Discovery Confidentiality Order will be required in these cases which the parties will submit by the date set forth in Exhibit 1.

(l) A pretrial conference may take place on _____:

Joint Response (C.A. Nos. 24-330 & 24-688): The parties' proposed schedule is attached hereto as Exhibit 1.

(m) Trial by jury or non-jury Trial?

Joint Response (C.A. Nos. 24-330 & 24-688): Non-jury trial.

(n) Trial date: _____.

Joint Response (C.A. Nos. 24-330 & 24-688): The parties' proposed schedule is attached hereto as Exhibit 1.

7. Do you anticipate any discovery problem(s)? Yes ___ No X. If so, explain.

8. Do you anticipate any special discovery needs (i.e., videotape/telephone depositions, problem with out-of-state witnesses or documents, etc.)? Yes _____ No X.

The parties anticipate that all witnesses will be made available for in-person depositions. Given the likelihood that foreign witnesses will be deposed, the parties will cooperate to either bring foreign witnesses to the United States or host the deposition of the foreign witness in a mutually agreeable location.

9. State whether this case is appropriate for voluntary arbitration (pursuant to L. Civ. R. 201.1 or otherwise), mediation (pursuant to L. Civ. R. 301.1 or otherwise), appointment of a special master or other special procedure. If no, explain why and state whether any such procedure may be appropriate at a later time (i.e., after exchange of pretrial disclosures, after completion of depositions, after disposition of dispositive motions, etc.).

Joint Response (C.A. Nos. 24-330 & 24-688): The parties do not believe these cases are appropriate for voluntary arbitration, mediation, appointment of a special master, or other special procedure at this time. The cases are in their nascent stages, and the parties have different views on the issues in this case. The parties agree to notify the court if they believe voluntary arbitration or mediation would aid resolution of these cases at a later time.

10. Is this case appropriate for bifurcation? Yes _____ No X_____.
11. We do _____ do not X_____ consent to the trial being conducted by a Magistrate Judge.
12. Pursuant to Local Patent Rule 2.1(a), the parties report the following from the 26(f) conference:

- (1) Proposed modification of the obligations or deadlines set forth in these Local Patent Rules to ensure that they are suitable for the circumstances of the particular case (see L. Pat. R. 1.3);

Joint Response (C.A. Nos. 24-330 & 24-688): The parties have addressed this issue in the proposed schedule attached hereto as Exhibit 1.

- (2) The scope and timing of any claim construction discovery including disclosure of and discovery from any expert witness permitted by the Court;

Joint Response (C.A. Nos. 24-330 & 24-688): The parties have addressed this issue in the proposed schedule attached hereto as Exhibit 1.

- (3) The format of the Claim Construction Hearing, including whether the Court will hear live testimony, the order of presentation, and the estimated length of the hearing;

Joint Response (C.A. Nos. 24-330 & 24-688): The parties will submit this information in the Joint Claim Construction and Prehearing Statement on the date set forth in Exhibit 1.

- (4) How the parties intend to educate the Court on the patent(s) at issue;

Joint Response (C.A. Nos. 24-330 & 24-688): The parties intend to educate the Court on the patents at issue through at least submissions to the Court, which may include *Markman* or other tutorial(s).

- (5) The need for any discovery confidentiality order and a schedule for presenting certification(s) required by L. Civ. R. 5.3(b)(2).

Joint Response (C.A. Nos. 24-330 & 24-688): The parties will submit a proposed discovery confidentiality order by the date set forth in Exhibit 1.

(6)

- (a) **The availability of and timing of any production of invention records (including inventor laboratory notebooks and analytical test results);**

Plaintiffs' Response (C.A. Nos. 24-330 & 24-688): With respect to L. Pat. R. 2.1(a)(6)(a), the parties agree that to the extent production of invention records (including inventor laboratory notebooks and analytical test results) is relevant to any party's claims or defenses and proportional to the needs of the case, and such materials are timely requested, Plaintiffs will produce any non-privileged invention records within the possession or control of Plaintiffs and pursuant to a reasonable search when required by L. Pat. R. 3.2 and prior to the deadline for the substantial completion of document production set forth in Exhibit 1.

- (b) **The availability of and timing of production of ANDA product research and development documents;**

Defendant's Response (C.A. Nos. 24-330 & 24-688): With respect to L. Pat. R. 2.1(a)(6)(b), the parties agree that to the extent production of ANDA product research and development documents is relevant to the parties' claims or defenses and proportional to the needs of the case, and to the extent such materials are timely requested, Defendant will produce any non-privileged ANDA product research and development documents within the possession or control of Defendant and pursuant to a reasonable search when required by L. Pat. R. 3.2 and prior to the deadline for the substantial completion of document production set forth in Exhibit 1.

- (c) **The availability and timing of production of ANDA product samples;**

Joint Response (C.A. Nos. 24-330 & 24-688): The parties are presently discussing a mutually agreeable date by which Defendant will produce timely requested samples.

- (d) **The date of conception and the date of reduction to practice for each patent asserted in the action, if applicable;**

Plaintiffs' Response (C.A. Nos. 24-330 & 24-688): With respect to L. Pat. R. 2.1(a)(6)(d), the parties agree that to the extent the date of conception and date of reduction to practice for the patents asserted in these actions is relevant to any party's claims or defenses and proportional to the needs of the case, documents evidencing the date of conception and date of reduction to practice for the patent-at-issue will be provided when required by L. Pat. R. 3.2 and prior to the deadline for the substantial completion of document production.

Joint Response (C.A. Nos. 24-330 & 24-688): Nothing in paragraphs 6(a)-(d) above is to be construed as a limitation on the parties' obligations to respond to

any timely served discovery requests under the Federal Rules of Civil Procedure.

(e) Each inventor's availability for deposition in the matter;

Plaintiffs' Response (C.A. Nos. 24-330 & 24-688): With respect to L. Pat. R. 2.1(a)(6)(e), Plaintiffs will investigate the inventors' availability for deposition and work in good faith to report to Defendant by February 18, 2025. The parties note that fact depositions, including inventor depositions, will not occur until after the date for substantial completion of document production identified in Exhibit 1. Inventors may be contacted only through Plaintiffs' counsel in these cases.

(f) Availability of foreign witnesses for deposition and foreign documents;

Joint Response (C.A. Nos. 24-330 & 24-688): With respect to L. Pat. R. 2.1(a)(6)(f), the parties will confer by February 18, 2025 regarding the availability of foreign witnesses for deposition within the United States and foreign documents and work in good faith to resolve any disputes relating thereto.

(g) Whether there is a 30-month stay and if so, when it ends;

Joint Response (C.A. No. 24-330): June 11, 2026

Joint Response (C.A. No. 24-688): June 26, 2026

(h) A date for substantial completion of document production and a method for determining compliance;

Joint Response (C.A. Nos. 24-330 & 24-688): The parties' proposed schedule is attached hereto as Exhibit 1.

(i) Any other issues or matters that a party believes are time sensitive.

Joint Response (C.A. Nos. 24-330 & 24-688): None at this time.

Dated: May 21, 2024

s/ Charles M. Lizza

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EXHIBIT 1¹

Event	Deadline
Initial Scheduling Conference (L. Pat. R. 2.1.(a))	May 28, 2024
Disclosure of Asserted Claims (L. Pat. R. 3.1.)	June 4, 2024
Parties Exchange Rule 26(a)(1) disclosures (L. Pat. R. 2.3.)	June 11, 2024
Parties submit proposed discovery confidentiality order (L. Pat. R. 2.2.)	June 11, 2024
Defendant serves non-infringement (L. Pat. R. 3.2A) and invalidity contentions (L. Pat. R. 3.3.)	June 27, 2024
Plaintiffs serve infringement contentions (L. Pat. R. 3.1.) and responses to invalidity contentions (L. Pat. R. 3.4A)	August 13, 2024
Parties exchange proposed claim terms for construction (L. Pat. R. 4.1.)	August 27, 2024
Parties exchange preliminary proposed constructions (L. Pat. R. 4.2.(a)) and identification of intrinsic and extrinsic supporting evidence (L. Pat. R. 4.2. (b))	September 17, 2024
Parties exchange identification of all intrinsic and extrinsic evidence they intend to rely upon in opposing any proposed claim construction and thereafter meet and confer to narrow issues (L. Pat. R. 4.2. (c))	October 1, 2024
Joint Claim Construction and Prehearing Statement (L. Pat. R. 4.3.)	October 17, 2024
Parties complete all fact discovery relating to claim construction (L. Pat. R. 4.4.)	November 18, 2024
Opening Markman briefs (L. Pat. R. 4.5. (a))	December 3, 2024
Parties complete all expert discovery pertaining to Markman issues (L. Pat. R. 4.5. (b))	January 10, 2025

¹ Agreement to email service (Fed. R. Civ. P. 5) – The parties agree that they should serve all pleadings, discovery requests and discovery responses by electronic mail. Service of discovery requests will be deemed to have been made on the day the electronic mail is sent by the sender, based on the time zone of the District Court.

Event	Deadline
Responding Markman briefs (L. Pat. R. 4.5. (c))	January 31, 2025
Plaintiffs to submit to the Court a proposed schedule for a Markman hearing (L. Pat. R. 4.6.)	February 14, 2025
Markman hearing (L. Pat. R. 4.6)	TBD
Last day to seek to add new parties or amend pleadings	30 days after the Court's <i>Markman</i> Opinion/Order
Substantial Completion of Document Production	May 2, 2025
Close of fact discovery	June 27, 2025
Opening expert reports	35 days after the Court's <i>Markman</i> Opinion/Order
Rebuttal expert reports	35 days after service of opening expert reports
Reply expert reports	28 days after service of rebuttal expert reports
Close of expert discovery	30 days after service of reply expert reports
Pretrial Order	TBD
Pretrial Conference	TBD
Trial	TBD
Thirty-Month Stay Expiration	June 11, 2026 (C.A. No. 24-330) June 26, 2026 (C.A. No. 24-688)